REMARKS

Claims 32-40, 42-43, and 46-47 are pending in the subject application. By this Amendment, applicants have amended claims 32, 33, and 46, and have canceled claims 34 and 35. Applicants maintain that the amendments to the claims raise no issue of new matter. Support for the amendments to claims 32, 33, and 46 can be found in the specification at, *inter alia*, page 6, lines 16-17. Accordingly, applicants respectfully request entry of this Amendment. After entry of this Amendment, claims 32, 33, 36-40, 42-43, and 46-47 will be pending and under examination.

Claim Rejections under 35 U.S.C. §103(a)

In the January 11, 2004 Final Office Action, the Examiner stated that claims 32-40, 42, 43, 46 and 47 are rejected under 35 U.S.C. §103(a) as being unpatentable over Wilson et al. (Patent No. 4,816,563) and Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86). The Examiner further stated that Ablashi et al. teach a method for treating patients suffering Chronic Fatigue Syndrome (CFS) with antigen specific transfer factor (TF), which is active against EBV, HHV-6 and CMV, and that Wilson et al. disclose a method for producing an antigen specific excreted transfer factor (TF) isolated from colostrum or milk of a bovine.

The Examiner further stated, in response to applicants' argument regarding a surprisingly efficacious result, that unless applicants point out that the HHV transfer factor specifically against serotype HHV6A or 6B can produce a more significant and unexpected result as compared to the HHV-6 transfer factor, then a composition comprising HHV6A or HHV6B will be considered obvious.

In response, applicants respectfully traverse the Examiner's rejection. Initially, applicants note that applicants' claimed invention clearly has a much better efficacy (90%) than the transfer factor of Ablashi et al. which is directed at all three of HHV6, EBV and CMV (50%). In light of the discussion in Ablashi et al. in combination with Wilson et al. positing that <u>two</u> viral infections can be important in controlling CFS (see Ablashi et al., page 85, last paragraph) and indicating that these two viral infections are EBV and HHV6, the fact that a product directed against subsets of only <u>one</u> of these virus types (i.e. HHV6) is 40% more effective than a transfer factor directed against both EBV and HHV6 *is* an unexpected result.

Moreover, the composition discussed in Ablashi et al. is for both EBV and HHV6, and for CMV. Nothing in Wilson et al. when taken in combination with Ablashi et al. teaches why a transfer factor specific for HHV6A or 6B would be expected to be much more effective at treating CFS than a transfer factor directed to both EBV and HHV6, especially with Abalshi et al. in combination with Wislon et al. suggesting that both EBV and HHV6 need be controlled in treating CFS. Accordingly, the claimed invention is not obvious in light of the prior art, and applicants respectfully request that the Examiner reconsider and withdraw the rejection.

Applicants additionally note that pending claims 32 and 33 recite the language "consisting essentially of". Applicants maintain that this language precludes any other component that would "materially affect the basic and novel characteristics" of the claimed invention (MPEP §2111.03). As Ablashi et al. state, their transfer factor comprises at least EBV and CMV as well as HHV6. Furthermore, the transfer factor was found to actively reduce EBV levels (see page 85, first col., penultimate paragraph), and this action is proposed by Ablashi et al. to be

involved in the treatment of CFS, i.e. material. Additionally, in Ablashi et al. in combination with Wilson et al. there is no suggestion to remove the EBV component from the product. Accordingly, the product discussed in the combination of references cited by the Examiner is materially different than that claimed by applicants. In light of this, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Claim Rejections under 35 U.S.C. §102(b)

The Examiner stated that claims 32-40 and 42-43 are rejected under 35 U.S.C. §102(b) as being anticipated by an advertisement by Chisolm Biological Laboratory in Positive Health News Report No. 17, Fall Issue 1998, p. 29, in view of an advertisement by Chisolm Biological Laboratory in Positive Health News, Fall 1997, p. 27.

In response, applicants respectfully traverse the Examiner's rejection. Applicants note that for a rejection on the ground of anticipation, every element of the claimed invention must be expressly or inherently described in a single prior art document (see MPEP, 2131). However, the advertisements cited by the Examiner do not expressly state each and every element, and thus the Examiner is inferring certain characteristics of the claimed invention are inherent in the advertised compounds.

Notably, the advertisements say nothing regarding production of HHV6a or HHV6b specific transfer factors, nor that the product is produced in a lactating bovid, nor that the animal is *immunized* with HHV6a or HHV6b (and not merely infected with HHV6a or HHV6b). Moreover, applicants note that a rejection based on inherency requires that the "the missing descriptive material matter must necessarily be present in the thing described in the

reference" (emphasis added), MPEP 21301.01 (III). Applicants maintain that this certainty requirement is not met by the rejection. For instance, there are other ways of making transfer factors other than from a lactating immunized mammal as claimed by applicants, e.g. from chicken bursas as mentioned in at least one Chisholm Immunfactor™ product description (see advertisement attached hereto as **Exhibit A**). Accordingly, the certainty requirement that the product be from an "immunized lactating bovid" is clearly not met. In addition, animals can be infected with HHV6 without being immunized, as is required in applicants' claimed product.

In response to the Examiner's statement that the "message delivered by the advertisement indicates that the Immunfactor is a colostrums product", applicants note that the two advertisements cited by the Examiner only mention the word "colostrum" in the statements "do not be fooled by simple dried colostrum/whey products" and "antigens which do not naturally occur in colostrum/whey products", i.e. the advertisements do not state whether the Immunfactor product is colostrum based. In regard to this, applicants again note that in at least one Chisholm Immunfactor™ product description (see advertisement attached hereto as **Exhibit A**) the transfer factors are described as being derived from chicken bursas (i.e. no colostrum), and not lactating bovids. Accordingly, the requirement that "the missing descriptive material matter must necessarily be present in the thing described" is again not met. Applicants further note that the website cited by the Examiner as a definition of transfer factor has a definition of the *natural* colostrums transfer factor in mammals, and is not necessarily the product described in the cited advertisements, especially in light of the chicken bursa source described above.

Accordingly, in light of the arguments set forth herein and the

uncertainties shown, the 35 U.S.C. §102(b) rejection is improper and should be withdrawn.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, apart from the $225.00 fee for a two month extension of time, is deemed necessary in connection with the filing of this Amendment. If any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

John P. White
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Attorney for Applicants
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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

6/13/05
Date

John P. White
Reg. No. 28,678

Natural Health Consultants

"A Natural Pharmacy"

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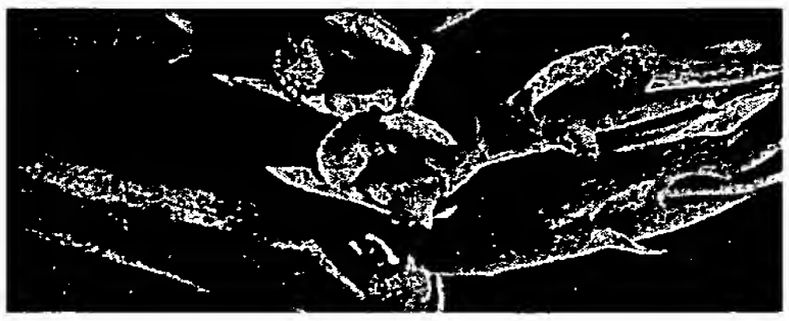

ImmunFactors

by Chisolm Biological laboratories

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WHAT IS IT?

ImmunFactor is transfer factor. This Transfer Factor (TF) is extracted from chicken bursa and is a oligoribonucleotide-peptide. The capsules also contain milk solids, yeast extract and yogurt.

WHAT DOES IT DO?

ImmuneFactor is an immune modulator.

ImmunFactor comes in several varieties:

ImmunFactor-1. It is targeted at the following organisms: HIV,

Applicants: Gregory B. Wilson et al.
U.S. Serial No.: 09/776,010
Filed: February 2, 2001
Exhibit A

HHV 6 (A), Herpes 1, Herpes 2, Mycobacterium avium, Candida albicans, Human tuberculosis, Bovine tuberculosis, Epstein Barr virus, Cytomegalovirus, Cryptosporosis, Pneumocystis carinii.

ImmunFactor-2. This formula contains antigen-specific transfer factors against Epstein-Barr Virus (EBV), Cytomegalovirus (CMV), Chlamydia pneumoniae, Borrelia burgdorferi (cell-wall deficient Lyme), Human herpes virus 6 (HHV6), Babesia, and Ehrlichia.

ImmunFactor-3 targets hepatitis A, B and C viruses.

ImmunFactor-4 is for people with all childhood illnesses, flu viruses or rabies.

ImmunFactor-5 contains multiple strains of Staphylococci, Streptococci and E. Coli.

ImmunFactor-8 contains CMV, EBV, Lymes, Chlamydia, HHV6, MMR, and 23 seria from the blood of autistic children. The protocol used for this condition is to use 1 and 4 each for 3 months, then use 8. Clinical and anecdotal reports have been very positive.

ImmunFactor-9 is for various strains of Mycoplasma.

ImmunFactor-10 is for Human Papilloma Virus (HPV.)

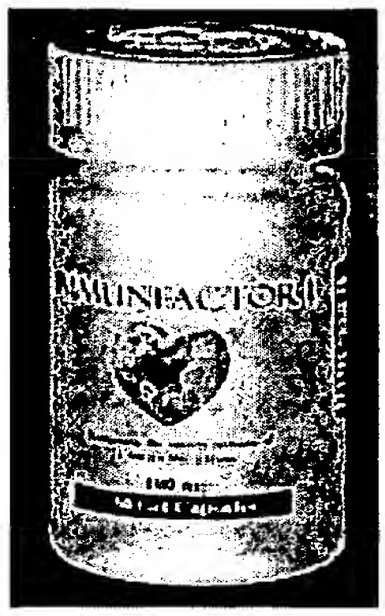
Also see Transfer Factor for a more general product.

CAUTIONS

Flu-like symptoms have occured involving night sweats and fever in those taking **ImmunFactors**. This is an indication that the immune system has awakened and is doing its job. There are no serious side-effects. Passage through several animal models in which disease states cannot survive coupled with intensive purification ensures that it is completely safe.

Bottles should be stored at 40 degrees F.

Personal



See Disclaimer.

DOSE

Take one capsule daily before the morning meal or as directed by a physician. All the **ImmunFactors** have a recommendation of at least three months, then pulse them for another two months. That is, taking one every four to five days after a person has gone at least three months.

NHC sells bottles of 30 capsules of **ImmunFactor-1,2,3,4,5,8,9 and 10** each for **$130.00**. The suggested retail price is $140.00.

ImmunFactor-1

1 Add To Shopping Cart

ImmunFactor-2

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ImmunFactor-3

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ImmunFactor-9

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ImmunFactor-10

1 Add To Shopping Cart

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CR I

These statements have not been evaluated by the U.S. Food & Drug Administration (FDA).
The products discussed are not intended to diagnose, treat, cure, or prevent any disease.

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Gerry Wolke, RPh.